

REMARKS

35 USC § 112

The Examiner rejected claims 1-21 rejected under 35 USC § 112 for failing to recite active, positive method steps (final office action, page 1, last line, and page 2, lines 1-2). The applicant disagrees, especially in view of amended claim 1. As amended herein, claim 1 now recites "...wherein the additive substantially binds to the cells and the particles and wherein the particles substantially bind to the cells and the additive..."

Claims 13-21 were rejected under 35 USC § 112 for reciting improper multiple dependent claims. The applicant disagrees, but nevertheless claims 13-21 have been amended according to the examiners suggestion.

New Matter

✓ Claim 4 was rejected under 35 USC § 112 as containing subject matter which was not described in the specification. The applicant disagrees, especially in view of amended claim 4. Amended claim 4 recites, "...the vessel has at least one wall that yields to pressure." The term "flexible" is defined in standard dictionaries as "yielding to pressure". Thus, the amendment to claim 4 is literally supported in the specification on page 6, lines 9-10.

35 USC § 103

Claims 1-21 were rejected under 35 USC § 103(a) as being obvious over *Doshi et al.* in view of *Kelland et al.* for reasons of record. The applicant disagrees, especially in view of amendments herein to claim 1. Amended claim 1, and all of claims 2-21 by virtue of their dependence on amended claim 1, recites the limitation "...receiving the sample in a vessel, wherein the vessel retains the sample within a plurality of confining walls..."

Doshi et al. teach an apparatus for red blood cell separation in which "... an absorbent pad is impregnated with a mixture of a lectin and beads of acrolein/iron oxide which have been coated with a lectin..."(column 16, lines 11-13). The *Doshi et al.* reference does not teach, suggest, or provide motivation utilizing a vessel, wherein the vessel retains the sample within a plurality of

confining walls. An absorbent pad is inconsistent with a vessel that retains a sample within a plurality of confining walls.

As a secondary argument, amended claim 1 further recites the limitation to separate "...the network from the substantially cell depleted portion by applying a force, wherein the force comprises a magnetic force." With respect to the magnetic force limitation in amended claim 1, the MPEP2143.03 states:

"...To establish prima facie obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. In re Royka, 490 F.2d 981, 180 USPQ 580 (CCPA 1974)..."

"...*Doshi et al.* explicitly teach filtration as a means of separation (e.g., column 15, lines 51-55, or column 21, claim 1, "primary filter"). There is simply no teaching, suggestion, or motivation in the *Doshi* reference to separate the network by employing a magnetic force. Even if the Office would argue that *Doshi*'s teaching of magnetizable beads inherently discloses a magnetic separation, the MPEP requires in section 2112:

...The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. In re Rijckaert, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993); ... In re Oelrich, 666 F.2d 578, 581-82, 212 USPQ 323, 326 (CCPA 1981); and "...In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art..."

The use of magnetizable beads is disclosed by *Doshi et al.* However, *Doshi et al.* teach that "...non-limiting examples include ...silica, ...glass beads, ...agaroase..."(column 9, lines 14-16), that "...many other inert particles that permit absorption, adsorption or immobilization of ...agglutinating agents...can also be used as nucleating particles..." (column 9, lines 19-23), and that "...many particles can be used, and the invention is not limited to any specific particles..." (column 9, lines 28-30). *Doshi*'s description of the particles and his explicit teaching of filtration as the means of separation do not reasonably support the allegation that a magnetic separation of the particles necessarily flows from the reference.

With respect to the *Kelland* reference, amended claim 1, and all of claims 2-21 by virtue of their dependence on amended claim 1, recite the limitation "...receiving the sample in a vessel, wherein the vessel retains the sample within a plurality of confining walls..."

Kelland teaches a method and apparatus for continuous magnetic separation of particles in a particle stream, in which "...particles in a slurry are continuously separated ...by passing the slurry through a separator"(column 3, lines 52-55). *Kelland* does not teach, suggest, or provide motivation to employ a vessel, wherein the vessel retains the sample within a plurality of confining walls. In contrast, in order to continuously separate the particles, *Kelland's* separator must allow the sample to flow through the vessel, which is inconsistent with the presently claimed limitation of retaining the sample.

The office further argues that (a) *Kelland* teaches the capacity of his method to separate particles according to magnetic susceptibility, independent of density, size and shape, such as the agglutinated cells in the method of *Doshi*, and (b) *Kelland* inherently teaches that his method can be utilized to separate larger elements, i.e., aggregates, cellular networks, etc. (page 6, first paragraph).

The Examiner correctly recognizes that *Kelland's* separation can be applied to magnetic separation of particles according to the particles magnetic susceptibility, independent of density, size, and shape of the particles. However, a particle of any density, size or shape is not a network. There is no support for the alleged separation of a network of particles (the agglutinated cells in the method of *Doshi*), and the applicant would appreciate if the Examiner could point out which part in *Kelland's* specification would support that notion.

With respect to the inherency argument, MPEP 2112 applies, which requires the examiner to provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art (vide supra). *Kelland* teaches a continuous separation of particles, wherein the separation is independent from density, size or shape of the particles. *Kelland* does not teach a formation of a cell containing network, let alone a separation of the network. A magnetic

cell containing network, let alone a separation of the network. A magnetic separation of individual particles does not necessarily imply a separation of a network of particles.

Thus, amended claim 1 and claims 2-21 by virtue of their dependence on claim 1 are non-obvious over *Doshi et al.* in view of *Kelland*.

REQUEST FOR ALLOWANCE

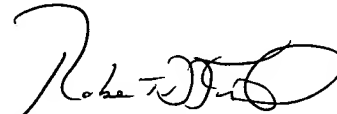
Claims 1-21 are pending in this application. The applicant requests allowance of all pending claims.

Respectfully submitted,

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